

REMARKS/ARGUMENT

Claim 11 has been amended to specify that each membrane consists essentially of a membrane containing epoxy groups chemically coupled to the protease inhibitor via the epoxy groups. Support for this amendment is found in the specification at page 4, lines 17-27, page 5, lines 14-20 and page 6, lines 12-16, so there is no issue of new matter.

Claims 11 and 14-15 stand rejected under 35 USC 103(a) as being unpatentable over Grano in view of Sugo U.S. 5,071,880, Burtin U.S. 6,248,238 and four other prior art references brought to the attention of the Examiner in connection with the Amendment filed on May 11, 2009. The Examiner reasons that Grano teaches that the protease inhibitor α -antitrypsin is grafted onto the membrane by first grafting glycidyl methacrylate (GMA) to the membrane, that GMA is known to contain epoxy groups according to the Sugo patent and that, in view of the references brought to the attention of the Examiner in the May 11, 2009 Amendment to the effect that amine and epoxy groups chemically couple and that all of the claimed protease inhibitors contain primary and/or secondary amine groups it would have been obvious to chemically couple the claimed amine-containing protease inhibitors to the GMA-grafted Grano membrane, and to incorporate the resulting protease inhibitor-containing membranes into the device of the Burtin patent. This rejection is respectfully traversed for the following reasons.

In issuing this rejection the Examiner appears to have overlooked the fact that Grano couples the protease inhibitor to the membrane via a diazotization reaction that utilizes not only GMA but phenylenediamine (PDA) wherein the PDA "was

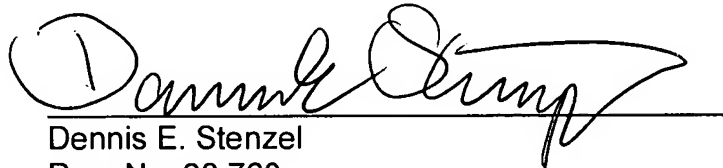
employed as a spacer between the [GMA]-grafted membrane and the protease inhibitor." Grano, page 298, right column, first sentence. There is no suggestion in Grano or in any other of the references relied upon to the effect that the Grano PDA spacer may be omitted. Indeed, Grano teaches that the coupling of the protease inhibitor to the membrane must be done with the PDA spacer via a diazotization reaction so as to not interact with the α -antitrypsin aminoacidic lysyl and methionyl residues, which are the residues responsible for inhibition of the protease (elastase) sought to be removed. Grano at page 301, paragraph bridging left and right columns. ("During immobilization of α -antitrypsin it is imperative not to involve these residues [lysyl and methionyl] responsible for inhibition. For this reason, we have chosen to immobilize α -antitrypsin via diazotization...." In other words, the Grano membrane would not be able to fulfill its stated function of inhibiting/inactivating the elastase protease if the coupling is not done via diazotization which requires the PDA spacer. It is well-settled that if a proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 221 USPQ 1125 (Fed Cir 1994).

Beyond the foregoing lack of motivation to modify Grano to directly couple the claimed protease inhibitors with the GMA-grafted membrane, it is pointed out that the transitional phrase "consists essentially of " in claim 11 means the membrane is limited to the components following that phrase and those that do not materially affect the basic and novel characteristics of the membrane. *In re Herz*, 190 USPQ 461 (CCPA 1976). This means that the claimed membrane excludes a second functional group such as PDA to chemically couple the protease inhibitor to the membrane.

As to Burtin, as previously pointed out, the Burtin apparatus merely incorporates a single membrane that has a single antiprotease agent electrostatically bound to the negatively charged sites within or on the surface of the membrane. Burtin at column 4, lines 33-45 and 53-56 and Examples 1-10.

For the reasons stated, early and favorable reconsideration is respectfully solicited.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this AMENDMENT is being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to: Mail Stop AMENDMENT, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

9/23/09
Date



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